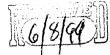


Whitehall-Robins
Five Giralda Farms
Madison, NJ 07940-0871
Telephone (973) 660-5500
Website address: http://heal

Website address: http://healthfront.com

6008 '59 657 39 72:34



September 3, 1999

Centrum[®] Silver

Notification of Statements on Dietary Supplement Labels

Elizabeth A. Yetley, Ph.D., R.D., Director Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, D.C. 20204

Dear Dr. Yetley:

Reference is made to Centrum® Silver, marketed by Whitehall-Robins Healthcare ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name:

Centrum Silver

Ingredients:

Multivitamin/Multimineral Supplement

Company Name/

Whitehall-Robins Healthcare

Address:

Five Giralda Farms

Madison, New Jersey 07940

Statements on the Carton Label:

- 1. Front of Label
 - Now with lutein. Helps maintain healthy eyes.*
- 2. Top Back Flap of Label

How Centrum Silver has been specially formulated ...

Lutein An antioxidant that helps maintain healthy eyesight.*

LET4262

The following structure/function claims were previously submitted in a separate notification on 6/28/99 for the Centrum Silver product that did not contain lutein. These below claims have not changed since that notification on 6/28/99, but are included here for completeness.

1. Top Back Flap of Label

How Centrum Silver has been specially formulated ...

- Vitamin B6 A higher level to help your body convert food to energy.* ∞
- Vitamin B12 Increased to help maintain heart health.* [∞]
- Calcium A higher level to help strengthen and maintain healthy bones.* [∞]
- Chromium A higher level to help your body metabolize sugars.* [∞]
- Vitamin E A higher level to help protect against cell damage.* [∞]
- Vitamin K An age adjusted level to support normal blood clotting.* [∞]
- Phosphorus An age adjusted level to help increase calcium absorption.* [∞]
 Compared to Centrum

2. Top Front Flap of Label

• Folic Acid and the antioxidants – Vitamins C and E – have been found in recent studies to have significant health benefits.*

In accord with 21 CFR §101.93, the disclaimer statement is bolded and boxed on all panels of the carton label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE

Eleanor F. Barbo Senior Director Regulatory Affairs